In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 20-155V

UNPUBLISHED

REBECCA VIANCOURT, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: December 14, 2022 Special Processing Unit (SPU); Influenza (Flu) Vaccine; Anaphylaxis

Howard Dale Mishkind, Mishkind Kulwicki Law Co., L.P.A., Cleveland, OH, for Petitioner.

Jennifer Leigh Reynaud, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION DISMISSING CASE [1]

On February 14, 2020, Rebecca Viancourt ("Petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*,[2] (the "Vaccine Act"). Petitioner alleges that she suffered anaphylaxis as a result of an influenza ("flu") vaccine administered on October 2, 2017. Petition at 1.

On November 6, 2020, I issued an Order to Show cause why this case should not be dismissed, due to Petitioner's apparent inability to meet the Vaccine Act's "severity"

[1] Although I have not formally designated this Decision for publication, I am required to post it on the United States Court of Federal Claims' website because it contains a reasoned explanation for the action in this case, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

requirement. On April 1, 2021, Petitioner filed a response to the Order to Show Cause, arguing that she has provided the necessary proof to maintain a Table claim. ECF No. 23. Respondent reacted on December 22, 2021, arguing for dismissal. ECF No. 28.

For the reasons discussed below, this claim is hereby **DISMISSED**.

I. Procedural History

Petitioner filed her petition on February 14, 2020, alleging she suffered from anaphylaxis caused by a flu vaccine administered on October 2, 2017. ECF No. 1. Petitioner further alleges that, since that time, she has required treatment for repeated episodes of anaphylaxis. *Id.* at 2.

On October 7, 2020, Respondent filed a Rule 4(c) Report arguing that compensation is not appropriate in this case because Petitioner has not established that she suffered the residual effects or complications of her initial, allegedly vaccine-caused episode for more than six months. Respondent's Rule 4(c) Report, ECF No. 18, at 6.

During a status conference on November 4, 2020, I noted that as the record stood, it appeared that Petitioner might not be able to show she suffered the residual effects or complications of her injury for more than six months. I therefore issued an Order requiring Petitioner to show cause why this case should not be dismissed. ECF No. 21, Order to Show Cause at 1-2. Petitioner filed a response on April 1, 2021, arguing that she had an original anaphylactic event due to the flu vaccination, with a subsequent three-year history of anaphylaxis sufficient to establish six months of symptoms. ECF No. 23, Petitioner's Brief in Response to Order to Show Cause ("Response") at 2-3. Respondent filed a reply on December 22, 2021, rebutting Petitioner's arguments. ECF No. 28, Reply to Petitioner's Response to Order to Show Cause ("Reply").

II. Factual Background

Petitioner received a flu vaccine on October 2, 2017. Ex. 2 at 1, 35. Within minutes, she developed anaphylaxis, for which she was given an injection of epinephrine and transferred to the emergency department. Ex. 7 at 12-13. She was discharged with a diagnosis of "[a]naphylaxic reaction due to vaccine," and given a four-day prescription of prednisone and Benadryl. Ex. 7 at 4-6.

Petitioner returned to the emergency department on October 4, 2017, with residual shortness of breath, chest tightness, weakness, and lightheadedness. Ex. 8 at 51-58. Petitioner's tests, including an exam, lab work, chest x-ray, and an EKG, were normal. She was diagnosed with myalgia, possibly from the epinephrine. That same day, she saw

Dr. Knauer, an allergist. Ex. 10 at 17-18. Dr. Knauer's impression was "apparent anaphylaxis to flu shot." *Id.*

Petitioner saw her primary care physician, Dr. Chillcott, on October 11, 2017, with reports of continued paroxysmal spasmodic cough since her flu vaccine. Ex. 4 at 420. She was diagnosed with moderate, persistent asthma with exacerbation and advised to take Singulair and avoid flu vaccines in the future. *Id.* at 422.

Petitioner returned to Dr. Knauer on November 15, 2017. Ex. 10 at 16. She had now developed systemic symptoms, including arm pain, shortness of breath shortly after receiving an intradermal allergy test for the flu vaccine. She returned that same day with weakness and erythema on her forearm where the test material was injected. Ex. 6 at 332.

Petitioner reported her anaphylactic reaction to her gynecologist on November 17, 2017, during a routine appointment. At that time, however, her examination was normal. Ex. 5 at 6-8. Petitioner also saw Dr. Chillcott on November 20, 2017 and exhibited a normal examination. Ex. 4 at 432.

On January 23, 2018, Petitioner was seen for symptoms unrelated to her alleged vaccine injury. Ex. 11 at 1-7. The following day she saw Dr. Sooriyapalan to establish care. Ex. 12 at 13.

Over two months later, Petitioner returned to Dr. Knauer on April 2, 2018, complaining of pain and swelling in her hands and fingers but denied shortness of breath. Ex. 10 at 12. Testing for inflammatory markers, autoimmune diseases, and immunoglobulin levels were within normal ranges. Ex. 6 at 281; Ex. 10 at 72, 75, 78-84. Another two months passed, and then (on June 3, 2018) Petitioner presented to the emergency department for lip and tongue swelling. Ex. 14 at 46-58. Petitioner returned to Dr. Knauer on June 4, 2018, and described her symptoms as a red, itchy rash all over her body and swelling of her tongue, mouth, and lips. Ex. 10 at 10. Allergy testing was conducted that was mostly unremarkable. *Id.* 28-62.

Petitioner saw a neurologist, Dr. Norton Winer, on June 13, 2018, with reports of arm numbness, tingling, and grip weakness. Ex. 13 at 1-4. Dr. Winer noted that Petitioner's symptoms "started after an anaphylactic reaction to a flu shot in October 2017." *Id.* at 1. Dr. Winer also noted, however, that immunologic testing had been negative. *Id.* On exam, Petitioner had no atrophy or weakness but "question of mild weakness bilateral opponens polloia". *Id.* at 3. An EMG/NCS study completed on July 16, 2018, was normal with no signs of denervation or reinnervation. Ex. 16 at 2.

On June 30, 2018, Petitioner was again seen in the emergency department for a rash, slightly enlarged tongue with numbness and tingling, and a feeling of throat swelling. Ex. 15 at 2-8. Petitioner returned to the emergency room following a bee sting on July 29, 2018. Ex. 17 at 6. She reported some difficulty breathing before taking Benadryl and using her EpiPen. *Id.*

In November of 2018 Petitioner twice returned to the emergency department for episodes including shortness of breath and itchy rashes. Ex. 18 at 12-18, Ex. 19 at 25-33, 60. She reported that "she gets idiopathic allergic reactions since last year". Ex. 18 at 12, Ex. 19 at 25. Both times, Petitioner used her EpiPen. Her tryptase level was normal and she was discharged after given medication. Ex. 12 at 60, Ex. 19 at 31, 60.

Petitioner saw Dr. Sooriyapalan on November 9, 2018, for a follow-up and to discuss test results. Ex. 6 at 199-201. Dr. Sooriyapalan noted that Petitioner was consulting an allergist and had multiple allergy tests done, which came back negative. *Id.* at 199.

Petitioner next sought care for hives and some throat tightness on December 13, 2019. Ex. 26 at 11; Ex. 30 at 19. She was given Benadryl, Pepcid, and Solumedrol. Ex. 26 at 11.

On May 4, 2020, petitioner saw allergist Dawn Zacharias, M.D., for idiopathic anaphylaxis. Ex. 30 at 7. Petitioner provided a complete copy of her medical records from Dr. Knauer and recounted her medical history, reporting that she had had "3 episodes of anaphylactic reactions," since she last saw Dr. Knauer in November 2019. *Id.* The physical exam was normal, but limited, due to Covid-19. *Id.* at 10. Dr. Zacharias diagnosed petitioner with idiopathic anaphylaxis and a bee sting allergy. *Id.* She commented, "The differential diagnosis for chronic urticaria [hives] is vast and can include autoimmunity, allergy, malignancy, parasite infection, immunologic disorder, thyroid dysfunction, vitamin D deficiency and hepatic or renal dysfunction." *Id.* at 7, 11. She ordered a comprehensive work-up and referred petitioner to Philip Lieberman, M.D. *Id.* at 11.

Petitioner returned to Dr. Zacharias on November 5, 2020. Pet. Ex. 30 at 15. It is unclear whether the results of any lab tests were discussed, but they were unremarkable. *Id.* at 30-34, 121. Petitioner advised that she was "attempting to go through the vaccine injury compensation program," and further related that "Dr. Knauer gave her an affidavit stating he believes" the vaccine caused her reaction. *Id.* at 15. Dr. Zacharias wrote that

she was "not willing to commit to the influenza causing her recurrent idiopathic anaphylaxis." *Id.*

On December 23, 2020, Petitioner saw Dr. Lieberman. Ex. 31 at 1. No records of the visit were filed, however Petitioner did provide a letter written by Dr. Lieberman to Dr. Zacharias. *Id.* Dr. Lieberman noted that the reason for Petitioner's visit was to discern the cause of her recurrent anaphylaxis, and whether it could be attributed to the influenza vaccine. Dr. Lieberman concluded that "our workup was not successful in eliciting a cause for her recurrent episodes". *Id.*

Petitioner submitted additional evidence including an affidavit from Dr. Knauer signed on November 15, 2019. Ex. 3. Dr. Knauer's affidavit consists of five paragraphs and states "it is my opinion…that [Petitioner's] vaccination was the likely cause of her anaphylactic reaction as well as her ongoing recurring episodes of anaphylaxis." *Id.* at 1. Further, Dr. Knauer opined that "the diagnosis of anaphylaxis which has persisted to the present date…are permanent in nature." *Id.*

III. Legal Standard

Before compensation can be awarded under the Vaccine Act, a petitioner must demonstrate, by a preponderance of evidence, all matters required under Section 11(c)(1), including the factual circumstances surrounding her claim. Section 13(a)(1)(A). In making this determination, the special master or court should consider the record as a whole. Section 13(a)(1). Petitioner's allegations must be supported by medical records or by medical opinion. *Id.*

In particular, a petitioner must establish that she suffered an injury meeting the Table criteria (*i.e.* a Table injury), in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination she received. If a petitioner establishes a Table injury the burden shifts to respondent to establish a more likely alternative cause. Section 13(a)(1)(A), 11(c)(1)(C)(i), 14(a). If a petitioner cannot establish a Table injury, he or she may pursue causation-in-fact under the legal standard set forth in *Althen v. Sec'y of Health & Hum. Servs.*, 418 F. 3d 1274, 1278 (Fed. Cir. 2005).

In addition to causation, a petitioner must also meet the requirements concerning the vaccination received, the duration and severity of petitioner's injury, and the lack of other award or settlement.[3] With regard to severity, a petitioner must show that she

[3] In summary, a petitioner must establish that she received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of her injury for more than six months, died from her injury, or

suffered the residual effects or complications of her injury or condition for more than six months after the administration of the vaccine. § 11(c)(1)(D)(i); *see Song v. Sec'y of Health & Hum. Servs.,* 31 Fed. Cl. 61, 65-66 (1994), aff'd, 41 F.3d 1520 (Fed. Cir. 2014) (noting that a petitioner must demonstrate the six-month severity requirement by a preponderance of the evidence). Finding that petitioner has met the severity requirement cannot be based on petitioner's word alone, though a special master need not base their finding on medical records alone. *See* § 13(a)(1); *see Colon v. Sec'y of Health & Hum. Servs.*, 156 Fed. Cl. 534, 541 (2021). Severity must be established regardless of whether the claim arises under the Table or is a causation-in-fact claim.

The terms "residual effects" and "complications" are not defined in the Vaccine Act. The Federal Circuit recently provided guidance on this topic, however, explaining that within the meaning of the Act a "residual effect" is "suffered" if it is a somatic condition that is detrimental (meaning endured with distress, especially painfully) and represents a lingering sign or symptom of the original injury. *Wright v. Secretary of Health and Hum. Servs.*,22 F. 4th 999, 1006 (Fed. Cir. 2022). A "complication" is similarly understood, but without representing an "essential part of the disease." *Id.*

IV. Analysis

Petitioner asserts, and Respondent does not contest, that she meets the core requirement for a Table anaphylaxis injury. Response at 1-2, Reply at 7-8. Specifically, Petitioner experienced anaphylaxis within minutes of her October 2, 2017 vaccination, and there is not preponderant evidence of an alternate cause. *See* 42 C.F.R. §§ 100.3(a)(XIV)(A); 100.3(c)(1) (Qualifications and Aids to Interpretation setting forth the requirements of establishing anaphylaxis as a Table injury).

But Petitioner's claim also requires that she show that she suffered the residual effects of her injury for more than six months. The single anaphylactic event must thus be demonstrated to have resulted in *some* subsequent symptoms or complications that persisted or unfolded for at *least* six months thereafter. For example, a petitioner who faints from the anaphylaxis and then hurts himself, requiring six or more months of treatment, would be able to show severity.

Petitioner asserts that she has met the requirements of a Table claim, and that she experienced recurrent anaphylaxis for more than six months. Response at 2. Further, she contends that "it is not incumbent on [her] to prove that her recurrent episodes of anaphylaxis were caused in fact by the vaccination, only that she has continued to

underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for her injury. *See* § 11(c)(1)(A)(B)(D)(E).

experience residual anaphylactic episodes or complications of her vaccine-related injury." Response at 2.

This is incorrect. The Act plainly obligates Petitioner to show, by preponderant evidence, that her alleged instances of recurrent anaphylaxis are the residual effects or complications of her vaccine-related injury. *Pearson v. Sec'y of Health & Hum. Servs.*, No. 17-489V, 2019 WL 1150044, at *11 n.13 (Fed. Cl. Feb. 7, 2019) (finding symptoms could not satisfy the six-month severity requirement because petitioner failed to persuasively link the alleged residual effects to her alleged initial anaphylaxis-type reaction). Unrelated subsequent harm, even if parallel to the initial injury, is not enough.

An examination of *Song,* 31 Fed. Cl. 61 is instructive. In *Song,* the Court of Federal Claims affirmed the dismissal of a petition which alleged that a child's learning and speech disabilities were due to his reaction to a diphtheria-tetanus-pertussis ("DPT") vaccine, because the petitioner failed to establish a causal connection between the subsequent disabilities and the then-Table injury of residual seizure disorder. There, the petitioner alleged that the child in question had a clear DPT-related seizure disorder, and then several months later (after meeting some developmental milestones) was noted to have delay in his expressive and receptive language functions. *Id.* at 63. The special master in *Song* found that the child had the Table injuries of encephalopathy and residual seizure disorder, but that the petitioner failed to establish a causal link between those injuries and his subsequent language deficits. *Id.* at 63–64, 65. In affirming, the Court noted that while the claimant did not need to show that the alleged delays *themselves* arose in the six month post-onset period, she did need to establish a causal relationship between the two. *Id.* at 66.

In this case, to meet the six-month severity requirement Petitioner would need to preponderantly show that her various symptomatic episodes in 2018[4] were casually linked to her initial anaphylaxis on October 2, 2017. However, the record reveals that two of Petitioner's treating allergists did *not* link the vaccine to Petitioner's subsequent anaphylaxis. Thus, Dr. Zacharias stated that she was "not willing to commit to the influenza causing her recurrent idiopathic anaphylaxis". Ex. 30 at 15. And Dr. Lieberman stated that he was not successful in determining a cause for Petitioner's recurrent episodes. Ex. 31 at 1.

In addition, there is a fairly lengthy period of time without evidence that Petitioner's single anaphylactic event was requiring treatment. And there is no additional evidence

[4] Those episodes included (a) pain and swelling in her hands and fingers on April 2, 2018 (Ex. 10 at 12), (b) lip and tongue swelling and a rash in June 2018 (Ex. 14 at 46-58; Ex. 15 at 2-8), (c) arm numbness and weakness reported on June 13, 2018 (Ex. 13 at 1-4), and (d) shortness of breath and itchy rashes in November 2018 (Ex. 18 at 12-18, Ex. 19 at 25-33).

(such as testing data or medical literature) that establishes any connection between a single incident of post-flu vaccine anaphylaxis and symptoms akin to what Petitioner reports. At most, Petitioner relies on Dr. Knauer's affidavit, wherein he states that "[Petitioner's] vaccination was the likely cause of her anaphylactic reaction as well as her ongoing recurring episodes of anaphylaxis." Ex. 3 at 1. However, Dr. Knauer does not articulate a basis for his conclusory opinion, nor does he cite to any medical literature or reference any medical records that would substantiate it. For that reason, I give his opinion little weight.

Given the above, there is not preponderant evidence that Petitioner's episodes of anaphylaxis were residual effects or complications of her initial episode – meaning that her Table claim cannot succeed even if the single close-in-time anaphylactic event meets the Table requirements.

Conclusion

The evidentiary record does not support Petitioner's contention that she experienced the residual effects or complications of her injury for more than six months after onset. Because Petitioner has failed to meet the severity requirement set forth in § 11(c)(1)(D)(i), Petitioner cannot establish entitlement, and therefore I must **DISMISS** her claim in its entirety. In the absence of a timely-filed motion for review (see Appendix B to the Rules of the Court), the Clerk shall enter judgment in accord with this Decision.[5]

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

[5] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by filing a joint notice renouncing their right to seek review.